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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,138	08/19/2004	Rango Dietrich	26230	1681

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/505,138	DIETRICH ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PT
6) ☒ Other: *NPL*.

DETAILED ACTION

Receipt of Amendment and Remarks filed therewith, filed 12/1/05 is acknowledged. Claims 1 – 17 are cancelled. Claims 18 – 65 are pending in this action.

Response to Arguments

Applicants traverse the rejection of claims 1 – 17, however, these arguments are deemed moot since those claims have been cancelled.

Priority

Applicant's claim to benefit of PCT/EP03/01650, filed 02/19/2003 is acknowledged. The priority papers have been forwarded to this office by the International Bureau.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

Instant specification, as originally filed, does not convey the limitation of a dosage form containing from 0.01 mg to 5 mg of roflumilast per dosage unit. Accordingly, a person of ordinary skill in the art would not recognize that Applicants were in possession of same at the filing date of the application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 – 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites "-oxide of the pyridine of the compound". It is unclear what is meant by "pyridine of the compound". Clarification is requested.

Claims 19 – 65 are rejected for depending on claim 18, thus incorporating the indefinite limitation.

Claim 24 recites "Kollidon®". If a trademark is used in a claim, the specification should recite both the generic name for the material and the source of the material. Instant specification does not recite the source of the material.

Claim 25 recites an improper Markush group. If the language "group consisting of" is used, then the members of the group must be listed in the inclusive, not in the alternative.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18 – 32, 36, 37, 58 – 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rennard et al., US 2003/0018071 A1 (Rennard) in view of Ghebre-Sellassie et al, US 6,677,362 (362).

Rennard teaches the PDE 4 inhibitors of instant claims, including roflumilast (paragraph 0015), preferably in a tablet or capsule form (paragraph 0020), and a method of administering same to an individual in amounts commensurate with that of instant claims (paragraph 0021 - 0022). Rennard further teaches immediate release formulations of these drugs, which contain excipients such as lactose, microcrystalline cellulose, starch, and magnesium stearate (Table 2).

Rennard does not teach the use of polyvinylpyrrolidone.

362 teaches that drugs with low water solubility are advantageously combined with polyvinylpyrrolidone to increase the bioavailability of such drugs (abstract). 362 further teaches that any drug with some limited water solubility may be used (claim 1, col. 3, lines 7 – 10).

The artisan would recognize that the drugs taught by Rennard, particularly roflumilast, have low water solubility.

Accordingly, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to add polyvinylpyrrolidone to the formulations of Rennard. The motivation to do so comes from 362, which teaches that the addition of polyvinylpyrrolidone will increase the bioavailability of the drug. The expected result

would be an immediate release dosage form with increased bioavailability. Since 362 teaches that nearly any drug with low water solubility can benefit from this manipulation, the artisan would enjoy a reasonable expectation of success.

With regard to the specific types of polyvinylpyrrolidone used, the specific amounts thereof, and the specific amounts of the drug and excipients, optimizing these to achieve the best result is well within the purview of the artisan. A person of ordinary skill in the art would find it obvious to carry out such optimization in order to achieve the best possible result.

Claims 33 – 35 and 38 – 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rennard and of Ghebre-Sellassie (362) as applied to claims 18 – 32, 36, 37, 58 – 65 above, and further in view of Remington: The Science and Practice of Pharmacy, 1995.

Rennard and 362 do not teach the use of corn starch, nor do they teach the granulation and related methods recited in instant claims.

Remington teaches that corn starch is a binder typically used in the tablet making art. Remington further teaches the various steps in granulating and related processes, as recited in instant claims, and that such steps are typical in the art of producing tablets.

Accordingly, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use corn starch as an additional binder in the invention of Rennard and 362, since such use of corn starch is well known in the art. As such, the artisan seeking appropriate ingredients for the tablet of Rennard and 362 would use

those well known in the art, such as corn starch, as taught by Remington, and would have a reasonable expectation of success at doing so.

With regard to the specific amounts of ingredients in the tablets, absent an unexpected result, the artisan would find it obvious to vary optimize the amounts of each of the ingredients, in order to achieve the best result. Such optimization is within the purview of the artisan. The expected result would be an immediate release formulation of roflumilast with increased bioavailability due to polyvinylpyrrolidone, which also contained other well-known excipients, such as corn starch.

With regard to the order of addition of the various ingredients during the granulation process, the artisan would recognize that the ingredients can be added in any order, absent an unexpected result. The particular order can be varied according to the convenience of the practitioner of the granulation process, as taught by Remington.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. CAS Registry 162401-32-3 is of interest for the teaching that roflumilast has low water solubility.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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